Union Calendar No. 177

105TH CONGRESS
1ST SESSION

H. R. 2469

[Report No. 105–306]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regulation of food ingredients, nutrient content claims, and health claims, and for other purposes.

OCTOBER 6, 1997

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 11, 1997

Mr. WHITFIELD (for himself, Mr. TOWNS, Mr. KLUG, Mr. HALL of Texas, Mr. GREENWOOD, Mr. MANTON, Mr. BURR of North Carolina, Ms. MCCARTHY of Missouri, Mr. BARTON of Texas, Mr. COBURN, Mr. UPTON, Mr. DEAL of Georgia, Mr. BILIRAKIS, Mr. ENGEL, and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Commerce

OCTOBER 6, 1997

Additional sponsors: Mr. GREEN, Mr. STRICKLAND, Mr. HASTERT, Mr. SAWYER, Mr. CANNON, Mr. BLILEY, and Mr. MCHALE

OCTOBER 6, 1997

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on September 11, 1997]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regula-

tion of food ingredients, nutrient content claims, and health claims, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Food and Nutrition Information Reform Act of 1997".

(b) REFERENCE.—Unless otherwise stated, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(c) TABLE OF CONTENTS.—The table of contents is as follows:

TITLE I—IMPROVING THE REGULATION AND LABELING OF FOOD

SEC. 101. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

Section 403(r)(4) (21 U.S.C. 343(r)(4)) is amended by adding at the end the following:

"(D) Subject to the time period in the last sentence of clause (A)(i), proposed regulations under this paragraph may be made effective upon publication at the discretion of the Secretary, notwithstanding the provisions of section 553 of title 5, United States Code, pending consideration of public comment and publication of a final regulation. Such regulations shall be deemed final agency action for purposes of judicial review.".

SEC. 102. PETITIONS FOR CLAIMS.

Section 403(r)(4)(A)(i) (21 U.S.C. 343(r)(4)(A)(i)) is amended—

(1) by adding after the second sentence the following: "If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner.";

(2) in the fourth sentence (as amended by paragraph (1)) by inserting immediately before the comma

the following: "or the petition is deemed to be denied"; and

(3) by adding at the end the following: "If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue such a proposed regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the proposed regulation did not occur within such 540 days.".

SEC. 103. HEALTH CLAIMS FOR FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end thereof the following:

"(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

"(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced rep-

resentation of the scientific literature, including a bibliography of such literature, relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(D) A claim submitted under the requirements of clause (C) may be made until—

"(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D)) under the standard in clause (B)(i)—

"(I) prohibiting or modifying the claim and the regulation has become effective, or

"(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.".

SEC. 104. NUTRIENT CONTENT CLAIMS.

Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding at the end the following:

"(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

"(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or

the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

"(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature, including a bibliography of such literature, relating to the nutrient level to which the claim refers;

"(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B),

and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(H) A claim submitted under the requirements of clause (G) may be made until—

"(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D))—

"(I) prohibiting or modifying the claim and the regulation has become effective, or

"(II) finding that the requirements of clause (G) have not been met, including finding that

the petitioner had not submitted all the information required by such clause; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.".

SEC. 105. REFERRAL STATEMENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended to read as follows:

"(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, then the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information for ____ content.' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.".

SEC. 106. DISCLOSURE OF IRRADIATION.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403B the following:

"DISCLOSURE

"SEC. 403C. (a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

"(b) In this section, the term 'radiation disclosure statement' means a written statement or symbol that discloses that a food or a component of the food has been intentionally subject to radiation.".

SEC. 107. IRRADIATION PETITION.

Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall—

(1) make a final determination on any petition pending with the Food and Drug Administration that would permit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act; or

(2) provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an explanation of the process followed by the Food and Drug Administration in reviewing the petition referred to in

paragraph (1) and the reasons action on the petition was delayed.

SEC. 108. GLASS AND CERAMIC WARE.

(a) IN GENERAL.—The Secretary may not implement any requirement which would ban, as an unapproved food additive, lead and cadmium based paints in the lip and rim area of glass and ceramic ware before the expiration of one year after the date such requirement is published.

(b) LEAD AND CADMIUM BASED PAINT.—Lead and cadmium based paint may not be banned as an unapproved food additive if it is on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim; and

(2) which is not, by design, representation, or custom of usage intended for use by children.

SEC. 109. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking "subsection (i)" and inserting "subsection (j)"; and

(B) by striking at the end "or";

(2) by striking the period at the end of paragraph (2) and inserting "; or";

(3) by inserting after paragraph (2) the following:

"(3) in the case of a food additive that is a food contact substance, there is—

"(A) in effect for such substance a regulation issued under this section prescribing the conditions under which such substance may be safely used and such substance and the use of such substance are in conformity with such regulation; or

"(B) a notification submitted under subsection (h) that is in effect."; and

(4) in the flush matter following paragraph (3) (as added by paragraph (3)), by inserting "or notification" after "regulation" each place it appears.

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

"Notification Relating to a Food Contact Substance

"(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a person manufacturing or sup-

plying a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the—

"(A) name of the person;

"(B) identity and intended use of the food contact substance; and

"(C) determination of the person that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A).

The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

"(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless, within the 120-day period, the Secretary—

"(i) makes a determination that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), or

"(ii) makes a determination under paragraph (3) with respect to the need for a petition under subsection (b) for such food contact substance,

and informs the person of such determination.

"(B) A determination by the Secretary under subparagraph (A)(i) shall constitute final agency action subject to judicial review.

"(C) A notification under this subsection shall be effective only with respect to the person identified in the notification.

"(3)(A) The notification process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and the person manufacturing or supplying the food contact substance agree that such person should submit a petition under subsection (b).

"(B) The Secretary may promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b) and shall consider criteria such as the probable consumption of a food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b) with respect to the food contact substance.

"(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

"(5) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.";

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: "The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to be no longer in effect."; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking "subsections (b) to (h)" and inserting "subsections (b) to (i)".

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of enactment of this Act.

SEC. 110. MARGARINE.

(a) SECTION 301(m).—Paragraph (m) of section 301 (21 U.S.C. 331) is amended by striking "section 407(b) or 407(c)" and inserting "section 407".

(b) SECTION 407.—Section 407 (21 U.S.C. 347) is amended to read as follows:

"OLEOMARGARINE AND MARGARINE

"SEC. 407. No person shall sell, or offer for sale, oleomargarine or colored margarine unless the principal display panel of such oleomargarine or margarine bears as one of its principal features the word 'oleomargarine' or 'margarine' which is in—

"(1) bold type on such panel;

"(2) a size reasonably related to the most prominent printed matter; and

"(3) lines generally parallel to the base on which the package rests as it is designed to be displayed.".

(c) ACT OF MARCH 16, 1950.—Sections 3(a) and 6 of the Act of March 16, 1950 (21 U.S.C. 347a, 347b) are repealed.

TITLE II—EFFECTIVE DATE

SEC. 201. EFFECTIVE DATE.

The amendments made by this Act shall take effect on the date of the enactment of this Act.

Amend the title so as to read: "A bill to amend the Federal Food, Drug, and Cosmetic Act and other stat-

utes to provide for improvements in the regulation of food, nutrient content claims, and health claims, and for other purposes.''.